VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 09/09/08

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Norman Ward, M.D.
Kathleen Boland, Pharm.D.
Lynne Vezina, R.Ph.
Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Erin Cody, M.D., OVHA
Stacey Baker, OVHA
Robin Farnsworth, OVHA
Jennifer Mullikin, OVHA

Guests:

Brian Korenda, GSK
Carl Pepe, GSK
Christina Carmody, Endo
David Spinney, Eli Lilly
Ed Terrien, M.D.
Erin Frisbie, Forest Pharmaceuticals
Jenifer Buttle, Merck
Mark Kaplan, Abbott
Molly Williams, Wyeth
Natalie Prairie, Forest
Neil Inhaber, Jazz Pharma
Richard Comshaw, ELi Lilly
Rod Francisco, Forest
Tracy Wall, Merck

Michael Scovner, M.D. Chair, called the meeting to order at 7:05 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The June 2008 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- OVHA Budget: At this point, all pharmacy programs remain intact. Staffing vacancies are not being filled as they occur. It is not anticipated that there will be proposals for pharmacy program cuts.

4. Medical Director Update: *Erin Cody, M.D., OVHA*

- Clinical Programs Update: No update.
- Prescriber Comments: No comments to report.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Suboxone®/Subutex®:
  The letter sent to prescribers of Subutex® was presented. Prior authorization is now required for all Subutex® users who were previously grandfathered. A discussion was held concerning the process to pursue for obtaining PA for Suboxone® users who are currently grandfathered.

Public Comment: No public comment.

Board Decision: The Board recommended obtaining PA for all Suboxone® users who are currently grandfathered. It was suggested that clinics and prescribers with many patients be contacted to help determine the best way to accomplish this.

- Asthma – Overuse of SABA:
  At the June meeting, a review of medication therapy for patients with asthma who had experienced an emergency room visit or inpatient admission was presented. While the Board had recommended a quantity limit be placed on short acting beta agonist inhalers to serve as an indicator of inadequate controller medication therapy, it was discussed that this could possibly place patients at risk if a short acting beta agonist was needed in an urgent situation.

Public Comment: No public comment.

Board Decision: The Board recommended that an educational bulletin be sent to pharmacists discussing the overuse of short acting beta agonist inhalers and the need for adherence to controller medication therapy in patients with asthma.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the October 1, 2008 PDL and/or Clinical Criteria update.

- Bystolic® (nebivolol): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to at least one preferred drug. A quantity limit of 1 tablet/day on the 2.5 mg and 5 mg tablet strengths was recommended.

Public Comment: *Dr. Ed Terrien, M. D.* – Discussed his experience with this drug.

Board Decision: The Board unanimously approved the MHP recommendations as described.

- Luvox® CR(fluvoxamine): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to at least two preferred SSRIs. (One of the trials must be the generic fluvoxamine). A quantity limit of two capsules per day is recommended.

Public Comment: Neil Inhaber, M.D., Jazz Pharma – Commented on the advantages of Luvox® CR compared to other SSRIs.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Pristiq® (desvenlafaxine): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has been started and stabilized on Pristiq®. (Samples are not adequate justification for stabilization) OR the patient has had a documented side effect, allergy, or inadequate response to at least 2 different antidepressants from the SSRI, SNRI and/or miscellaneous antidepressant categories (May be preferred or non-preferred). A quantity limit of one tablet per day was recommended.

Public Comment: *Brian Erickson, M.D.* – An email from Dr. Erickson supporting the addition of Pristiq® to the PDL was shared with the Board.

Board Decision: The Board unanimously approved the MHP recommendations as presented.

- Treximet® (sumatriptan/naproxen): Not recommended for addition to the PDL. Coverage would require PA with criteria for approval being that the patient has had a documented side-effect, allergy or treatment failure with 2 preferred products and is unable to take the individual components separately. A quantity limit of 9 tablets per 30 days is recommended.

Public Comment: *Carl Pepe, GSK* – Commented on the benefit of the two drugs together in one tablet.
Brian Korenda, GSK – Commented on the clinical data with Treximet®.
Morris Levin, M.D. – An email from Dr. Levin supporting the addition of Treximet® to the PDL was included in the Board packet.

Board Decision: The Board approved the MHP recommendations as stated. The vote was not unanimous (one member disagreed with requiring PA and voted to place Treximet® in a preferred position).

- Veregan® (sinecatechins) Ointment: Not recommended for addition to the PDL. Coverage would require PA with criteria for approval being that the patient has a confirmed diagnosis of condylomata acuminata AND the member has had a documented side effect, allergy, or treatment failure with Aldara® cream AND the duration of therapy does not exceed 16 weeks AND a quantity limit of 15 grams (1 tube) per 30 days is not exceeded.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as presented.

New Dosage Forms:

- Lamisil® Granules (terbinafine): Not recommended for addition to the PDL. Coverage would require PA with criteria for approval being a diagnosis of Tinea capitis, medical necessity for a specialty dosage form (i.e., inability to swallow tablets, dysphagia), and an adverse event, allergy, or a contraindication to griseofulvin suspension. In addition, the duration of therapy should be limited to 6 weeks. An updated allylamine antifungal managed category was presented that clearly outlined the duration of approval based on diagnosis.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board requested that a notation be made underneath the table to specify that griseofulvin suspension, although not a member of the class of allylamine antifungals, is available without PA to treat Tinea capitis.

- Emend® Injection (fosaprepitant): Not recommended for addition to the PDL. Approval criteria should include that the medication will be prescribed by an oncology practitioner, the patient requires prevention of nausea and vomiting associated with moderate to highly emetogenic cancer chemotherapy, the patient has a medical necessity for the IV administration (i.e, inability to swallow capsules, dysphagia) and that the requested quantity does not exceed one 115 mg vial per course of chemotherapy. Patients with multiple courses of chemotherapy per month will be approved for quantities sufficient for the number of chemotherapy courses.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as presented.

- Protonix® Pak (pantoprazole) (delayed release oral suspension): Not recommended for addition to the PDL. It was recommended that this product require prior authorization with a quantity limit of 1 packet per day. More detailed criteria will be presented at next month's meeting.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)* (Public comment prior to Board action)

- Antidepressants – rename/restructure of class "Novel":
  It was proposed that the "Novel" antidepressant class be divided into 2 separate categories which would be the "SNRI" antidepressants and the "Miscellaneous" antidepressants. The criteria for PA requiring medications remain unchanged.

Public Comment: No public comment.

Board Decision: The Board approved the two new antidepressant categories as presented.

- Mental Health Medications: Maximum Doses: It was proposed that the wording describing maximum doses and the doses documented in the mental health medication categories be updated. It was proposed that the dosing read "FDA maximum recommended dose = XX mg/day" where the dose would be the maximum dose from the FDA approved prescribing information (package insert). Previously, the doses listed were 25 % above (1) the FDA maximum recommended dose or (2) commonly accepted maximum doses as approved by the DUR Board in 2005. The latter were based on comments from the Psychiatric Subcommittee and community practitioners in order to ensure that access to needed doses would not be limited for patients with difficult to treat conditions. The previous wording of "suggested maximum dose" was, on occasion, mistakenly interpreted to mean the DUR Board was recommending the prescribing of the stated dose routinely. This change in wording will not limit access to needed doses. This will be described in the "Management of Mental Health Medications" in the Clinical Criteria Manual.

Public Comment: No public comment.

Board Decision: The Board approved the change in wording and maximum dose listings for the mental health medications.

- Cymbalta® (fibromyalgia):
  The new FDA approved indication for Cymbalta® of fibromyalgia was discussed. Previously, the Board had reviewed the literature available regarding the medication treatment of fibromyalgia. It was recommended that PA continue to be required for Cymbalta® and that approval follow the current Lyrica® approval criteria for fibromyalgia. The criteria for approval would be the patient has had a documented side effect, allergy, or treatment failure to TWO drugs from the following: gabapentin, tricyclic antidepressant, SSRI antidepressant, SNRl antidepressant, miscellaneous antidepressant, or cyclobenzaprine. It was recommended that the look-back for previous used medications be automated for the depression indication only and that physicians would be required to call or fax for PA for other indications. Currently, none of the indications have an automated look-back.

Public Comment: Richard Comshaw, Eli Lilly – Discussed results of clinical trials of Cymbalta® and other medications in fibromyalgia.

Board Decision: The Board unanimously approved the recommendations as presented.

- Lyrica® (differentiation of diagnoses):
  It was reported by the MedMetrics Clinical Call Center that patients who do not meet the criteria based on previously tried medications for some indications are having prescriptions process at the pharmacy because of the broad variety of medications that may be used for fibromyalgia and the automated look-back step therapy that is now in place. It was recommended that the look-back for previous trials of medications for fibromyalgia would no longer be automated but that the automated step therapy look-back for epilepsy and neuropathic pain continue as in place now.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as presented.

8. New Drug Classes:

- No new drug classes.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Compounded Products (including topical analgesics): The compounded topical analgesic products are not currently managed by OVHA. To determine if changes to the current policy are required, utilization data and the available literature evaluating compounded topical analgesics were reviewed. Pharmacy claims for compounded topical analgesic products during the 3-month time period from January 1, 2008 to March 31, 2008 were reviewed. There were a total of 7 OVHA members who filled a prescription for a compounded topical analgesic product. Two out of 7 members received refills on their prescriptions resulting in 11 total paid claims. Due to the low utilization of compounded topical analgesics reported in the OVHA population and published reports of safe and effective use; it is recommended that no changes to the current policy be implemented at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously agreed that compounded topical analgesics did not need to become a managed drug category.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 06/19/08 - 08/28/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Vytorin® - possible increased cancer incidence: The FDA informed healthcare professionals that the Agency is investigating a report from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial of a possible association between the use of Vytorin® and a potentially increased incidence of cancer. A larger percentage of subjects treated with Vytorin® were diagnosed with and died from all types of cancer combined when compared to placebo during the 5-year study. No changes in criteria or coding are recommended at this time. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as presented.

- Tysabri® - two new cases of PML: The FDA informed healthcare professionals of two new cases of progressive multifocal leukoencephalopathy (PML) in European patients receiving Tysabri® monotherapy for multiple sclerosis for more than one year. Prescribing information for Tysabri® will be revised to include information informing prescribers and patients that cases of PML have occurred in patients taking Tysabri® as monotherapy when previous cases in patients with multiple sclerosis were seen in combination with other immunomodulatory therapies. No changes in criteria or coding are recommended at this time. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as presented.

13. <u>Adjourn</u>: Meeting adjourned at 9:20 p.m.

Next DUR Board Meeting
Tuesday, October 14, 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.